REMARKS

Claims 110-115 are pending. Claims 59-109 and 116 have been cancelled without prejudice or disclaimer.

I. Election of Species

Applicants acknowledge the withdrawal of claims 63-65, 67-92 and 94-109 from consideration at this time as being drawn to a non-elected species. Applicants respectfully submit that, due to an inadvertent error, method claims 113-115 incorrectly depended from composition claim 109. Thus, each of claims 113-115 has been amended to depend from method claim 110. As such. Applicants request reconsideration of the withdrawal of claims 113-115.

II. 35 USC § 112

Claims 59-62, 66, 93, 110-112 and 116 stand rejected under 35 USC § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim that which is considered the invention. With respect to the majority of the rejections, Applicants thank the Examiner for her suggestions and have amended the claims accordingly.

A. "analogs"

The Office Action asserts that the use of the term, "analogs" is unclear. Specifically, because such a term is not defined in the claims, the claims are indefinite. Applicants direct the Examiner's attention to the specification (as embodied in the PCT Publication No. WO 98/10786), wherein such analogs are defined. Analogs of somatostitn are defined in the first full paragraph of page 3 as, any analog compound of somatostatin which biologically activates one or more somatostatin receptors, while analogs of diazoxide and cylothiazide are defined as compounds which affect the receptor being adenosine 5'-triphosphate sensitive K^+ channels (page 19, lines 30-32).

B. Effective Dosage

The Office Action asserts that the recitation of "calculated on octreotide" renders claim 111 unclear. In response, the offending term has been removed to clarify that this claim is not to be limited to octreotide.

Additionally, the Office Action states that because the dosages recited by claims 111 and 112 do express a concentration nor the dosages in grams, moles or liters, these claims are unclear. However, Applicants respectfully submit that any particular concentration is considered within the scope of these claims. For example, pages 22-23 present dosages used in the experiment detailed by the specification, in which rat populations were given injections in a 0.09% NaCl soluition of identical volumes, but different concentrations, i.e., Group A was 40 μg/kg/day, while Group B was 20 μg/kg/day, wherein both doses are within the scope of the invention.

III. 35 USC § 102 and § 103

Claims 59-62, 66, 93, 110-112 and 116 stand rejected under 35 USC § 102(b) as allegedly being anticipated by, and § 103(a) as allegedly being unpatentable over Higuchi et al. (U.S. Patent No. 4,462,991), Veber et al. (Life Sci, Vol. 34, pp. 1371-1378, 1984), Orskov et al. (Metabolism, Vol. 45, No. 2, pp. 211-217, 1996), Kollind et al. (Acta Endocrinologica, Vol. 118, pp 173-178, 1988), Williams et al. (Scandinavian J. of Gastroenterology, Supplement, 1986 119, 73-83), and Fueessl et al. (Klin. Wochenschr., 64, Supp. 5, 188, 186).

The Office Action appears to state that a high level of insulin is a symptom of the X syndrome, and therefore, the delay of the secretion of insulin comprises treatment of the syndrome. However, none of the cited references describes the treatment presently claimed because none of the references relate to the treatment of Syndrome X of Reaven.

Orksov et al. discusses a derivative of somatostatin, i.e., octreotide, being given to diabetic patients who are dependent upon insulin (Type I). Veber et al. discusses applying a cyclic analog of somatostatin, having a length of 6 amino acids to diabetic mice. Kollind et al. teaches to apply somatostatin to diabetics being dependent upon insulin (Type I). Williams et al.

discloses giving to diabetic patients not dependent upon insulin (Type II), a derivative of somatostatin, i.e., octerotide (SMS 201 995). As can be clearly seen, each of these references are concerned with the treatment of diabetes with somatostin and its derivatives. However, it is commonly known that Type I diabetes affects 10% of diabetics and 5% of the mature population of the Western world, while 90% of diabetics have Type II diabetes.. In contrast, Syndrome X affects 25% of the Western world.

Additionally, it is commonly known that Syndrome X and Type II diabetes are distinct medical conditions. While both may include insulin resistance, it is generally understood that Syndrome X and Type II diabetes are independent conditions. See, e.g., http://www.cacr.ca/news/2000/0009reaven.htm (Article I) and http://www.woundcare.org/newscol1n3/ar1.htm (Article II), both of which are provided as Attachment II.

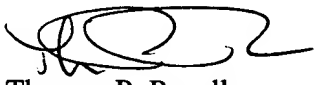
Thus, Applicants respectfully present that the methods presented by the cited references are for the treatment of diabetes, not Syndrome X of Reaven. Because none of the cited references even mentions Syndrome X, its is not understood how these references, either alone or in combination, can be said to disclosed a method of treating syndrome X.

Additionally, because somatostain and its derivatives may be useful in the treatment of insulin deficiency, at best, these references teach that somatostatin may be used as a research tool for investigating its effectiveness with respect to other diseases the symptoms of which include insulin deficiency. However, such an analysis is deemed "obvious to try" and may not be the basis of an obviousness rejection under 35 USC § 103(a). See MPEP § 2145. Reconsideration is respectfully requested.

IV. Conclusion

In view of the above, it is respectfully submitted that all objections and/or rejections are overcome. Thus, a Notice of Allowance is respectfully requested.

Respectfully submitted,



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ATTACHMENT I - Marked-Up Claims

110. (Amended) A method for the treatment of symptoms of syndrome X by administering to a patient a pharmaceutical composition [according to Claim 59] comprising a pharmaceutically effective dosage of a compound selected from the group consisting of [among] somatostatin or one of its analogs, diazoxide or one of its analogs, cyclothazide or [cyclothazideor] one of its analogs and [analogsand] metaformin.

111. (Amended) A method according to Claim 110, wherein the pharmaceutically effective dosage [(calculated on octrotide)] does not exceed 50 µg/kg/day.

112. (Amended) A method according to Claim 110, wherein the said dosage does not exceed 40 µg/kg/day.

113. (Amended) A method according to Claim 110, [Claims 109] wherein the analog is Octrotide which is applied in the form of an injection in a 0.9% saline solution.

114. (Amended) A method according to Claim 110 [Claims 109], wherein said dosage does not exceed 8 mg/kg/day in the treatment of the active ingredient [(calculated on diazoxide)] in adults, and does not exceed 15/mg/day in the treatment of children.

115. (Amended) A method according to Claim 110 [109], wherein the amount of metformin applied does not exceed 2.5 g/day divided into 2-3 portions.

ATTACHMENT II - Articles I & II